

MANUAL

ALEA instructions for screening database

ID: HDC-OP-CDM-342-2-MN-8

KMS Version: 2

1. PURPOSE

This document provides instructions, guidelines and background information for the screening database using the Electronic Data Capture (EDC) system of ALEA (version 17.1) , as implemented by the Erasmus MC – HOVON Data Center.

2. SCOPE

This manual is applicable Local Data Managers with registration rights, Site Principal Investigators, Central Data Managers and users with only Patient registration rights.

3. TERMS & ABBREVIATIONS

Term (Abbreviation <i>if applicable</i>)	Definition
CRF	Case Report Form
EDC	Electronic Data Capture
HCD	HOVON Data Center
ICF	Informed Consent Form
LI	Local Investigator (new: Site PI (Site Principal Investigator))
Site PI	Site Principal Investigator

4. REQUIRED & RELATED DOCUMENTS

#	Type	Document title
N.A.		

5. DOCUMENT HISTORY

Version	Date	Description of change
1	01APR2019	ALEA instructions for screening Database (Original version)
2	13MAR2020	Changed picture in chapter 3 and chapter 5.

6. MANUAL

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2. ALEA

ALEA is supported by most commonly available web browsers (i.e. Internet Explorer 7.0 and higher, Mozilla FireFox, Google Chrome, Safari (Apple), and Android 4.0 and higher).
Used documentation: Forms Vision ALEA data management User Manual v.5.4.

This ALEA Screenings database manual is suitable for HOVON studies for which patients need to be screened. Whether a screenings database is used is mentioned in the protocol of the trial or is specified by the trial manager.

2.1 Workflow

The following workflow is followed when a patient is registered in the screenings database (see also flow shown below).

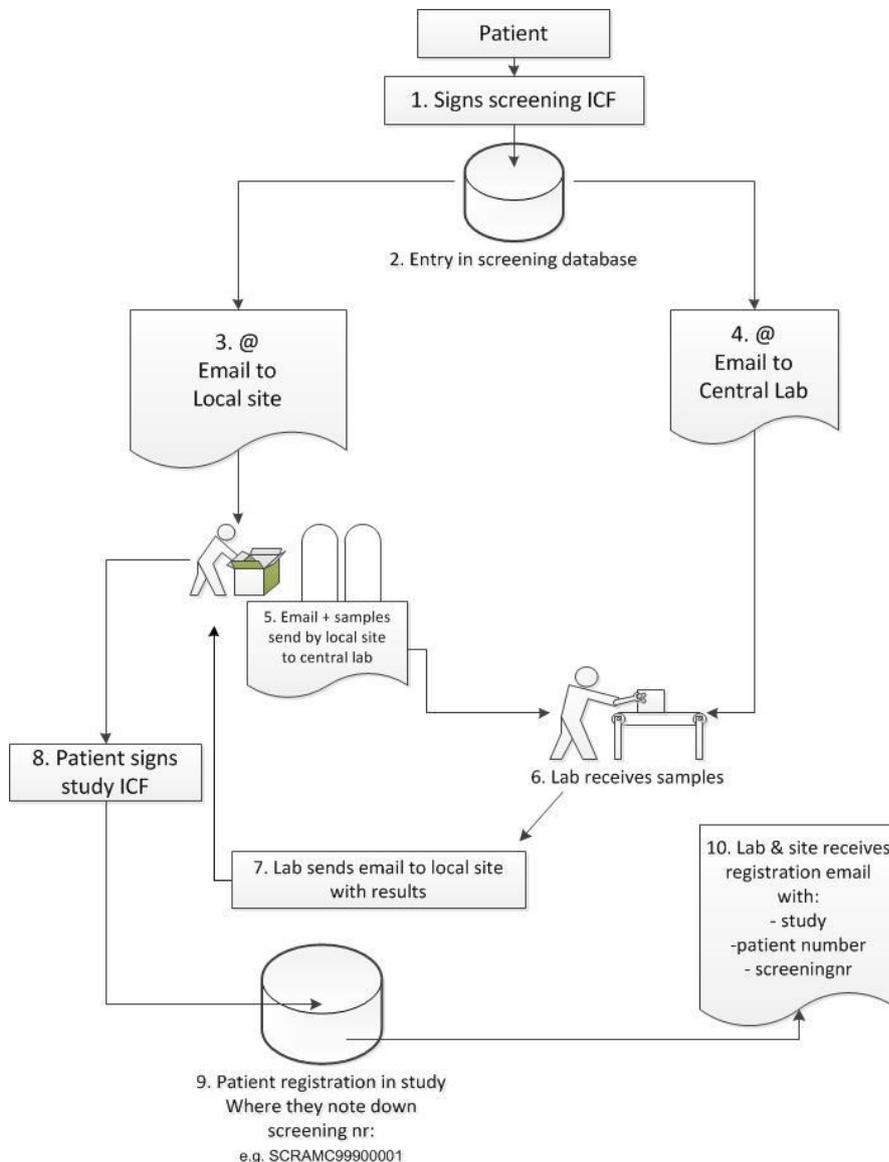
If a patient is suitable to enter the screenings database, the patient first needs to sign a general screenings ICF (1). The patient is entered into the screenings database (2) and the site receives an email with further instructions and a screening number which is clearly different from a usual Patient ID (the mark up starts with SCR (from Screening) and the site name (for example AMC) and 999 before the 5 digits of the sequence number) (3). Also the central lab is notified that a patient is entered for screening, so that they know that samples are coming their way (4).

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Following the instructions received in the email, the site sends samples (marked with the screening number) together with the print out email to the central lab (5) using the screening lab kit as is explained in the lab manual. The lab analyses the samples (6) and sends the results by email to the site (7) (using the email addresses previously filled out in step 2). If the patient is eligible for the study, the patient signs the study ICF (8). Then the patient can be registered within the study database (9), during that step also the screening number is requested to be able to connect the screening number with the Patient ID.

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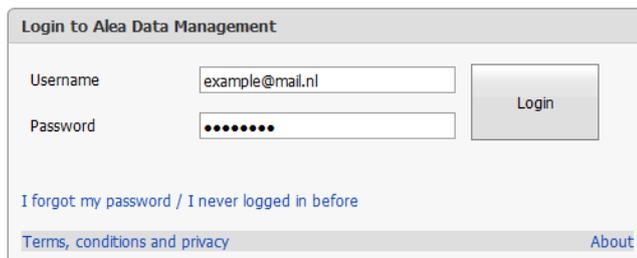
2.2 Request for account

For the screenings database a separate account access is necessary. However, opposed to the study databases, the screenings database will also accept general email accounts (e.g. trialbureau@hospital.nl) to be used to register new patients. If you wish to request an account to access the screenings database, please fill out a ALEA user account form, that can be found on the HOVON website.

2.3 Login

The URL to the ALEA portal is: <https://aleaclinical.com/Hovon/DM/DELogin.aspx>

It is recommended to bookmark this link in the Favorites section of your web browser.



Logging in for the first time

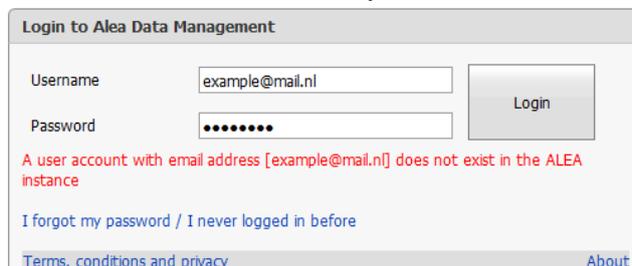
Through the option “I forgot my password / I never logged in before” you can send a request to receive an email (from EMC TENALEA Mail Service info@formsvision.net) with a one-time link.

! **IMPORTANT:** For security reasons, this link expires within 30 minutes after receiving the email. Check your spam or junk mail folder if no email is received.

The following message may appear:

No account has been provided yet → please contact the HOVON Data Center (hdc@erasmusmc.nl)

The email address is incorrectly entered → check the spelling



After logging in for the first time, using your email address as username, the following message appears:

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Your password has expired. Please enter a new password

TENALEA.NET services - Terms of use BEST EFFORT contracts

FormsVision Software Legal Policies, Rules and Regulations and Terms of Service.
Last Updated December 6, 2011

Terms of Service/Acceptable Use Policy

1. GENERAL.
This Acceptable Use Policy ("AUP"), including the following list of ~~Disallowed~~ Activities, encourages the responsible use of the web sites (the ~~example@mail.com~~ available by FormsVision BV. and/or its affiliated companies and subsidiaries (collectively, "FormsVision" "us" or "we"), and any features and functionality made available through the Sites including without limitation hosting services (collectively, the "Services"). This AUP is incorporated by reference into the Terms of Use for the Sites and is an integral part of your Agreement with FormsVision. The purpose of this AUP is to delineate the type of actions and content that are contrary to our mission and philosophies, as well as to ensure that your use of our Sites, and

I agree with the terms and conditions for the use of TENALEA.NET services

By agreeing with the terms and conditions, the following screen will be displayed. Here you can enter a (new) password. Choose a password with a minimum length of 8 characters, containing at least one digit (e.g. 1,2,3).

Once your password has been successfully changed/accepted, the account has been activated and ALEA is accessible.

Your password has expired. Please enter a new password

Password expiration
The password you set now will expire in 365 days. When you log in after your password has expired, you are prompted to renew your password after logging in. You can change your password at any time by selecting *forgotten password* in the TENALEA login screen, or by selecting *Change password* from the data management menu.

Password length
The password you set should have a minimum length of 8 characters.

Your password has expired. Please choose a new password, enter it in both fields and confirm by pressing set password.

Accountname

New password

Confirm new password

Your password has been changed

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3. Open screenings database

If you have access to multiple studies, you will enter a Study Selection page upon login. This split-screen shows an overview of all studies (including the 'study' called screenings database).

Open the Screenings database 'study' either by clicking the Enter button of the highlighted study or the Enter button in the header of the summary section.

The screenshot displays the 'Study Selection' page in the ALEA system. The interface is split into two main sections. On the left, a table lists studies with columns for 'Study', 'Status', 'Last used', and 'Last activity'. The 'SCREENINGSDATABASE' study is highlighted in grey. On the right, a summary section for the 'SCREENINGSDATABASE' study is visible, showing details such as Type (eCRF), Role (Data management administrator), Study Scope (International), and Study phase (Pilot). The HOVON logo is present in the bottom right corner of the interface.

Study	Status	Last used	Last activity	Open
SCREENINGSDATABASE	Open	09-Mar-2020 09:00:00	06-Mar-2020 15:22:08	enter
HO150	Open	03-Mar-2020 14:57:00	09-Mar-2020 08:58:24	enter
HO156	Open	20-Feb-2020 16:39:00	06-Mar-2020 12:01:30	enter

SCREENINGSDATABASE
Screenings database

Type: eCRF
Role: Data management administrator
Study Scope: International
Study phase: Pilot
Current patient accrual: 167
First entered patient: 29-Apr-2019
Last entered patient: 06-Mar-2020
Last activity: 06-Mar-2020 15:22:08
Open queries: 0
Open replied queries: 0
Open reraised queries: 0

HOVON

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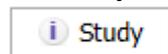
4. Study overview

A study homepage is organized according to the following tabs:

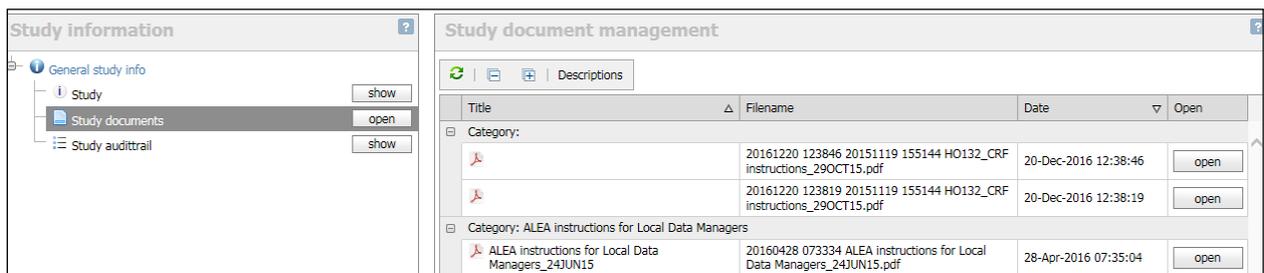


Please note that these tabs are only available if you are not working in a Patient Dossier (Chapter 5).

The Study tab shows the study details:



Here you can access study documents (if available, e.g. CRF instructions) or information on study accrual (with the option to adjust the chart settings).



The screenshot shows two panels. The left panel, titled 'Study information', contains a tree view with 'General study info' (show), 'Study' (show), 'Study documents' (open), and 'Study audittrail' (show). The right panel, titled 'Study document management', shows a table of documents with columns for Title, Filename, Date, and Open. The table contains three rows of document information.

Title	Filename	Date	Open
Category:			
	20161220 123846 20151119 155144 HO132_CRF instructions_29OCT15.pdf	20-Dec-2016 12:38:46	open
	20161220 123819 20151119 155144 HO132_CRF instructions_29OCT15.pdf	20-Dec-2016 12:38:19	open
Category: ALEA instructions for Local Data Managers			
ALEA instructions for Local Data Managers_24JUN15	20160428 073334 ALEA instructions for Local Data Managers_24JUN15.pdf	28-Apr-2016 07:35:04	open

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5. Patients overview

By selecting the Patients tab from the study homepage, the eCRF can be accessed.

The screenshot shows the 'Study info' page for the HOVON study. The main content area displays the HOVON logo and the following information:

- Long study title: Screenings database
- Description:
- Study Scope: International
- Study phase: Pilot
- First entered patient: 29-Apr-2019
- Last entered patient: 06-Mar-2020
- Current patient accrual: 167
- Last activity: 06-Mar-2020 15:22:08
- Queries: Open (0), Replied (0), Reraised (0)

The default study overview appears.

The screenshot shows the 'Patients' tab in the SCREENINGSDATABASE interface. The table displays the following data:

Institute	Clinician	patient key	Clinician and institute	Registration date	Last update	Dossier
NL -Zwolle-Isala (Isala)	Screening Isala	Isala-SCR-99900004	Screening Isala, Dummy (Isala)	14-Feb-2019	15-Feb-2019 09:30:41	open
NL -Zwolle-Isala (Isala)	Screening Isala	Isala-SCR-99900003	Screening Isala, Dummy (Isala)	08-Jan-2019	08-Jan-2019 11:49:51	open
NL -Zwolle-Isala (Isala)	Screening Isala	Isala-SCR-99900002	Screening Isala, Dummy (Isala)	08-Feb-2018	08-Feb-2018 10:20:51	open
NL -Zwolle-Isala (Isala)	Screening Isala	Isala-SCR-99900001	Screening Isala, Dummy (Isala)	08-Feb-2018	08-Feb-2018 07:44:43	open

You will see that the clinician is in this case a dummy name as the screenings database will be used for more than one trial with different Site Principal Investigators (previously called Local Investigators).

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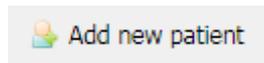
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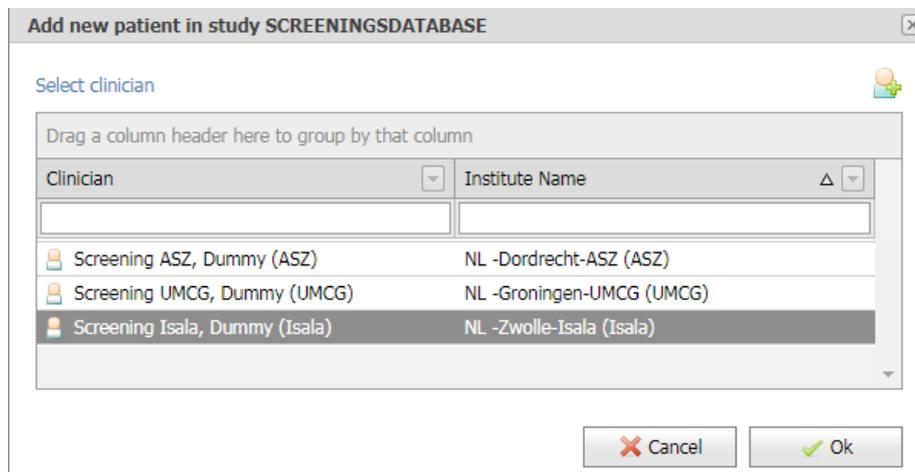
KMS Version: 2

6. Add new patient

To add a new patient, click on the top right button:



If your account has access to multiple sites to register patients for, please select the applicable site (with the dummy Site PI). This step is not shown for accounts that have access to just one site.

A screenshot of a software dialog box titled "Add new patient in study SCREENINGSDATABASE". The dialog has a close button (X) in the top right corner. Below the title bar, the text "Select clinician" is displayed in blue. To the right of this text is a small icon of a person with a plus sign. Below this is a section with the instruction "Drag a column header here to group by that column". This section contains two columns: "Clinician" and "Institute Name", each with a dropdown arrow. Below these columns are two empty text input fields. Underneath the input fields is a list of three items, each with a small person icon on the left. The first item is "Screening ASZ, Dummy (ASZ)" with "NL -Dordrecht-ASZ (ASZ)" to its right. The second item is "Screening UMCG, Dummy (UMCG)" with "NL -Groningen-UMCG (UMCG)" to its right. The third item is "Screening Isala, Dummy (Isala)" with "NL -Zwolle-Isala (Isala)" to its right. The third item is highlighted with a dark gray background. At the bottom of the dialog are two buttons: "Cancel" with a red X icon and "Ok" with a green checkmark icon.

Thereafter fill out the items as shown below. All red marked items are obligatory.

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Screening

SCREENINGS DATABASE

GENERAL SITE DATA

Registrating person [name]

Please note: the email addresses provided below will receive an email with the sample results - once analyzed. Please double check if the email addresses are correctly entered, to prevent any difficulties for the central lab.

Local investigator [email]

Local coordinator (or research nurse) [email]

Responsible physician [email]

General email address (not obligatory) [email]

PATIENT DATA

Age at registration

Sex

Date informed consent signed [dd/mm/yyyy]

DISEASE AREA

Disease area

Sample date (of material to be sent, take first sample date if there are multiple dates) [dd/mm/yyyy]

General site data

Registrating person

Name of the person who is filling out this form.

Local Investigator

Email address of the (potential) site PI (or otherwise known as Local Investigator).

Local Coordinator

Email address of the person who is locally coordinating the sample shipment.

Responsible physician

Email address of the physician. This can be the same as the Local Investigator, of course the email with the results will only be send out once.

General email address

Here you can fill out other email addresses that need to receive the central lab results. Please divide them by semicolon (;) if there are multiple addresses.

Please note, only the account registering the patient for screening, will receive a screening notification from ALEA with the screening number.

Patient data

Age at registration

Current age of the patient.

Sex

Sex of the patient.

Date informed consent

This is the screenings Informed Consent date.

Disease area

Disease area

Select the disease area which is concerned, for instance AML/MDS.

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Diagnosis analysis request Once the disease area is filled out a further specification is requested. This might be just one analysis request, but it can be more than one.

Sample date Date on which the sample was taken. If there are multiple dates, take first date.

If there are mistakes made in the filled out data, the fields are marked with a red dotted line and at the right side of the screen in section 'Audittrail and discrepancies' is visible what is viewed as incorrect.

The screenshot shows the 'Screening' form interface. On the left, the 'SCREENINGS DATABASE' section includes 'GENERAL SITE DATA' (Registrating person: test), 'PATIENT DATA' (Age at registration: 1000, Sex: female, Date informed consent signed: 02/04/2019), 'DISEASE AREA' (AML/MDS), and 'DIAGNOSIS' (ANALYSIS REQUEST AML-FLT3 ITD + FLT3 TKD AND AML-IDH1 + IDH2 MUTATIONS). A 'Sample date' field is empty and marked with a red dotted line. A 'Submit' button is at the bottom. On the right, the 'Audittrail and discrepancies' panel shows three items: 'Age at registration (AGE)' with a 'value discrepancy' message '- This is not a valid age.', 'Date informed consent signed (DICF)' with a 'value discrepancy' message '- Date cannot be in the future', and 'Date sample (DSAMPLE)' with a 'value discrepancy' message '- Please answer this question'. Each item has a 'resolve' button.

Once all obligatory fields are filled out and all discrepancies are solved, the submit button becomes active.

Submit

Once you submit the data the screening number is shown on the screen:

The dialog box displays the message: 'The following SCREENING number has been assigned to this patient: Isala-SCR-99900006'. An 'Ok' button is located at the bottom right of the dialog.

Also an email is sent out to the account email address that was logged in.

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! **IMPORTANT:** He/she should forward it to other site personnel that might need this information (like the person who takes the sample and should write down the screening number on the sample)

Once the screening form was submitted, you can close the registration form at the top right corner.

Close registrationform 

Screening Form status : **Submitted**
Lock status :  

SCREENINGS DATABASE

GENERAL SITE DATA

Registrating person [name]

Please note: the email addresses provided below will receive an email with the sample results - once analyzed. Please double check if the email addresses are correctly entered, to prevent any difficulties for the central lab.

Local investigator [email]

Local coordinator (or research nurse) [email]

Responsible physician [email]

General email address (not obligatory) [email]

PATIENT DATA

Age at registration

Sex

Date informed consent signed [dd/mm/yyyy]

DISEASE AREA

Disease area

DIAGNOSIS

ANALYSIS REQUEST AML-FLT3 ITD + FLT3 TKD AND AML-IDH1 + IDH2 MUTATIONS

Sample date (of material to be sent, take first sample date if there are multiple dates) [dd/mm/yyyy]

! **IMPORTANT:** It is strongly recommended to check the filled out data once more to see if no spelling mistakes were made in the email addresses and the age and sample date is correctly provided. This will make sure that the central lab is able to correctly identify the samples and send the results to the correct people.

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If there was a (spelling) mistake made, please inform the HOVON Data Center immediately (hdc@erasmusmc.nl) so that the screeningsdatabase can be updated and the central lab can be informed.

7. Query management, reports and ALEA

Although the query tab is visible for this screenings database, no queries will be raised on these forms. Also no reports are available for this screenings database. The last tab contains information about ALEA. This section is not applicable to you.

SCREENINGSDATABASE AleaGateway: TTP Logged in as: Idmreg@erasmusmc.nl Logged in since: 01-11-2017 10:00:00

Study Patients Queries Reports User Alea

8. User

The tab User displays your User Profile, containing information about the role that has been assigned to you (e.g. Local Data Manager with registration rights) and the settings that are in place. Via Change password, you can provide a new password if you wish to do so.

SCREENINGSDATABASE AleaGateway: TTP Logged in as: Idmreg@erasmusmc.nl Logged in since: 01-11-2017 10:00:00

Study Patients Queries Reports User Alea

User

- User profile
- Login and access information
- Change password**
- Application settings
 - Notification settings
 - DM Application - user settings
- Dropbox
 - Dropbox files

User password - Idmreg@erasmusmc.nl

Accountname:

New password:

Confirm new password: